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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,684	12/11/2001	Jonathan Caldwell Wright	3869/026	1015

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EXAMINER	
RAGONESE, ANDREA M	

ART UNIT	PAPER NUMBER
3743	19

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,684	WRIGHT ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33,36,40-50,53,57-69,72,80-85,87-92,94-99 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-33,36,40-50,53,58,59,64,72 and 89-92* is/are allowed.

6)☒ Claim(s) *57,60-63,65-69,80,81,87,88,94-99 and 104* is/are rejected.

7)☒ Claim(s) *82-85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on December 31, 2003 has been entered. Examiner acknowledges that **claims 23, 26, 28, 29, 32, 36, 40-43, 45, 46, 49, 53, 58-60, 63-65, 68, 72, 81, 82, 87-89, 91, 94-96** and **104** have been amended and **claims 20-22, 34, 35, 37-39, 51, 52, 54-56, 70, 71, 86, 93** and **100** have been cancelled.

2. Due to Applicant's typographical error, as stated in Paper No. 12, original **claim 104** was inadvertently overlooked during the examination of the originally presented invention [see page 16]. However, **claim 104** contains a broader recitation of the claimed invention than **claims 62, 63, 72** and **96**, which were previously rejected in Paper No. 7. Since this claimed subject matter was addressed in an action on the merits for the originally presented invention, the rejection of **claim 104** made in this action is deemed proper and is therefore made FINAL.

Inventorship

3. In view of the papers filed December 31, 2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding joint inventor, Alison Mary Hansford.

4. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Response to Arguments

5. Applicant's remarks, filed December 31, 2003, regarding **claims 60-63** and **65-69**, have been fully considered but they are not persuasive [see page 14]. It appears that Applicant believes that subject matter found in original **claim 60** was noted by Examiner to be allowable, but this is indeed not the case. Incorporating the subject matter of **claim 54** into **claim 60** does not make **claim 60** allowable. As stated in Paper No. 10, **claim 60** was rejected under 35 U.S.C. 102(b) as being anticipated by Berthon-Jones (US 5,704,345) or by Brydon (WO 98/52467) [see pages 3-5]. Accordingly, the 102(b) rejections of **claims 60-63, 65** and **66** made in the previous action are deemed proper and are therefore made FINAL. In addition, the 103(a) rejection of **claims 67-69** made in the previous action is deemed proper and is therefore made FINAL.

6. Applicant's arguments, filed December 31, 2003, regarding **claims 80-85, 87, 88** and **94-99**, have been fully considered but they are not persuasive [see pages 14-15]. As broadly interpreted based on Applicant's disclosure, the prior art of record can still be applied to the claimed invention. Brydon (WO 98/52467) discloses a CPAP treatment apparatus that has the ability to change between different types of CPAP treatment, such as changing the therapeutic level of treatment pressure being delivered to the patient. Therefore, as broadly recited and based on the support found in the Applicant's specification, the 102(b) rejection of **claims 80-85, 87, 88** and **94-99** is deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claim 57** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, **Claim 57** is rejecting to as being of improper dependent form for being dependent on cancelled **claim 56**. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Accordingly, **claim 57** has not been further treated on the merits.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 60-63, 65, 66, 94-99** and **104** are rejected under 35 U.S.C. 102(b) as being anticipated by Berthon-Jones (US 5,704,345). Berthon-Jones discloses a CPAP apparatus, as shown in Figure 2, that includes all of the features of **claims 60-63, 65, 66, 94-99** and **104**, specifically including a computer **62** programmed with instructions for controlling a blower to deliver breathable gas at

a pressure above atmospheric to a patient and calculating a stroke indicator from a flow signal indicative of a patient's airflow.

11. Berthon-Jones discloses that the controller **62** is programmed to calculate a number of indicators in the form of Index values that represent information about the patient's condition, and subsequently serve as qualitative measures upon which further processing is based (column 6, line 66-column 7, line 20). For example, the controller **62** calculates the Breathing Index and then compares this index to the Threshold value to determine if a patient is experiencing apnea. The controller **62** then calculates the Obstruction Index, which, when compared to the Threshold value, indicates the degree of obstructive apnea in the patient. In other words, the Obstruction Index is a function of the obstructive apnea in the patient. Once apnea has been determined by calculating the Breathing Index, the patency of the airway is determined by calculating the Patency Index to produce a leak-compensated Patency Index (column 15, lines 40-64). The Patency Index is a function of the central apnea in a patient. This can be seen in Figures 1 and 16.

12. Berthon-Jones further discloses that the apparatus includes instructions for identifying and delivering subsequent treatment based on one or more of the stroke indicators calculated; the subsequent treatment being in the form of different types of CPAP therapy (column 3, lines 22-37), as shown in Figures 1 and 16.

13. With respect to the medium with stored instructions recited in **claims 60-63, 65, 66, 94-99** and **104**, it is the Examiner's position that a recording medium having these instructions is inherent to a computer that performs the analysis recited therein. For example, the apparatus for analysis disclosed by Berthon-Jones must include such a medium with stored instructions for performing the analysis disclosed because a computer/controller must utilize stored instructions in order to perform the analysis/calculations described. Accordingly, the apparatus disclosed by Berthon-Jones anticipates **claims 60-63, 65, 66, 94-99** and **104**.

14. **Claims 60-63, 80, 81, 87, 88, 94-99** and **104** are rejected under 35 U.S.C. 102(b) as being anticipated by Brydon (WO 98/52467). Brydon discloses all of the features recited in **claims 60-63, 80, 81, 87, 88, 94-99** and **104** including a computer that processes a flow signal and that is programmed with instructions as recited. Specifically, the computer **101** delivers a breathable gas over a period of time, e.g. overnight. The system measures the number of apneas and hypopneas per hour (i.e. the first index) and adjusts the pressure delivered to obtain a number of apneas and hypopneas per hour less than a threshold number, e.g. 6 per hour. Different types of CPAP treatment (i.e. the ranges of pressures necessary to reduce the number of apneas and hypopneas per hour to below the threshold) are selected when the number of apneas and hypopneas exceeds the threshold (page 28, line 24-page 29, line 30).

15. In addition, the system disclosed by Brydon includes instructions for querying for sleep history in the form of producing a report at the end of the diagnostic period that indicates physiological observations (e.g. movement and the like) that informs the choice of CPAP treatment (page 29, lines 25-30).

16. With respect to **claims 94** and **95**, it is the Examiner's position that such a recording medium is inherent to a computer that performs the analysis recited therein. For example, the apparatus for analysis described by Brydon must include such a medium with stored instructions for performing the analysis disclosed because a computer/controller must utilize stored instructions in order to perform the analysis/calculations described. The Applicant should note that the Examiner maintains the same position with respect to the remaining claims directed to a "recording medium." Accordingly, **claims 94-99** and **104**, as well as **claims 60-63, 80, 81, 87** and **88**, are anticipated by the medium that must be part of the apparatus disclosed by Brydon.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. **Claims 67-69** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones (US 5,704,345) in view of Burton (WO 98/50095). Berthon-Jones discloses a positive pressure apparatus comprising all the limitations recited in **claims 67-69**, with the exception of the processor including instructions for identifying a change in drug therapy based on the stroke indicator, evaluating changes in the stroke indicator to assess the efficacy of an administered drug and storing the stroke indicator in a database of patient information. However, the use of an apparatus with these instructions was known at the time the invention was made. Specifically, Burton teaches the use of an apparatus for

controlling drug delivery or gas to a patient. A drug delivery module is controlled by a processor **5** to deliver drug therapy to a patient in accordance with physiological data collected from a patient and to determine the efficacy of the amount of drug delivered to the patient based on the detected physiological data (page 5, line 12-page 6, line 2 and page 18, line 22-page 19, line 14). Burton also discloses that the apparatus can also store a monitored event type such as an apnea with its time and duration. Such stored information comprises a database. See the discussion of "Step 8" beginning on page 19. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Berthon-Jones to include the recited instructions for changes and evaluation of drug therapy and storage of the stroke indicator as taught by Burton. One would have been motivated to do so in order to be able to respond to a respiratory disorder that is not responsive to positive pressure therapy (page 5, lines 12-31) and to validate the information monitored by the apparatus (page 19, lines 22-29).

Allowable Subject Matter

21. **Claims 23-33, 36, 40-50, 53, 58, 59, 64, 72** and **89-92** are allowed.

22. **Claims 82-85** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **(703) 306-4055**. The examiner can normally be reached on Monday through Thursday from 8 am until 4 pm ET.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

amr
March 2, 2004

Henry Bennett
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